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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,998	08/23/2001	Malcolm J. Simons	005493.P001	1983

7590 07/16/2004

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

**Advisory Action**

Application No.

09/935,998

Applicant(s)

SIMONS, MALCOLM J.

Examiner

Bradley L. Sisson

Art Unit

1634

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 30 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 30 June 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Bradley L. Sisson  
Primary Examiner  
Art Unit: 1634

Continuation of 2. NOTE.

Continuation of 5. does NOT place the application in condition for allowance because: While applicant has sought to amend claim 3, for example, by inserting language previously found in claims 26-28, the insertion of said language does not overcome the aspect of the method of claim 1, or even of claim 3, fairly encompassing the amplification of the entire chromosome. It is noted with particularity that claim 1 calls for the amplification of "genomic DNA." Clearly, the chromosome in which the target sequence is found fairly meets this limitation, as does the short arm of Chromosome 6, where the HLA genes are located. Further, claim 3, even as proposed in the instant Rule 1.116 response, defines the non-coding regions in terms of what they "comprise." Again, such language fairly encompasses the chromosome in which the gene, and its associated non-coding regions, 5'-untranslated sequence, 3'-UTR, regulatory sequences and/or any intervening sequence.

Acknowledgement is made of applicant having provided via an appendix to their response, a listing of the names of the genes in the HLA region. While the showing lists 42 genes, and applicant asserts that the specification as filed provides an adequate showing of primes that can be used, it is noted that the claimed method is not drawn to simply identifying the various genes, but rather, is drawn to identifying mutations in the various alleles of the genes that comprise the HLA region, and to then determine critical information that is to be associated therewith, e.g., relatedness to disease occurrence. As seen in the 1999 publication of Schreuder et al., there were 425 alleles reported for the three genes HLA-A, HLA-B, and HLA-DRB1. In their 2001 update, Schreuder et al., report that there are now known to be 550 alleles in these same three genes. A review of the disclosure fails to locate, and applicant's response fails to identify, where the disclosure teaches the primers needed to detect not only the 550 alleles now known to exist, but the alleles that exist in the remaining 39 genes listed in the appendix provided by applicant, much less identify those mutations in those unidentified alleles which, by a mechanism not described or known, are to be related to critical issues of genetic disease (claim 5).

For the above reasons and those presented in the Final Office action of March 2004, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 112, first paragraph, is maintained.